

**REMARKS**

By way of this response, Applicants have canceled claims 1-71 and added new claims 72-107. Accordingly, claims 72-107 are now pending in the present application. The new set of claims is consistent with the previous invention/species election.

**Rejection of Claims 16, 29 and 30 under 35 USC §101**

In the Office Action, claims 16, 29, and 30 were rejected under 35 U.S.C. §101 in view of claims 1, 28, and 29 of U.S. Patent No. 6,893,460. Applicants do not agree with the Examiner's determination because claims 16, 29, and 30 did not include certain limitations of the earlier claims. Nevertheless, these claims have been canceled and Applicants assert that the new claims are not the same invention as any claims in any previous patent.

**Rejection of Claims 1-11, 14, 15, 17-22, 25, 26, 33, 36, 39, 40, 67 and 70 under 35 USC §101**

Claims 1-11, 14, 15, 17-22, 25, 26, 33, 36, 39, 40, 67 and 70 were rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over a variety of claims in U.S. Patent No. 6,893,460. Applicants respectfully traverse this rejection because each of the independent claims of the '460 patent include limitations that are not present in the pending claims. Specifically, claim 1 of the '460 patent provides that the valve assembly is rolled over the support stent at the inlet, and claim 28 provides that the valve assembly is made with a coiled wire coated with cutting material.

The Examiner asserts that the original and now canceled claims are broader than and thus are not patently distinct from the claims of the '460 patent. However, the standard for obviousness-type double patenting is whether a claim in an application is merely an obvious variation of an invention claimed in the patent (see MPEP §804, p. 800-21). The analysis is the same as with a standard section 103 obviousness rejection, with the exception that the underlying patent is not prior art. It is therefore not true, as a *per se* matter, that just because a claim is broader than an earlier claim that it is obvious. In the present instance, the new independent claims include elements that are not in claims 1 and 28 of the '460 patent, and omit elements that are. Because of the replacement of the originally rejected claims with the new claims, however, Applicants eschew a detailed explanation until the Examiner has had a chance

to review this response and decide whether the obviousness-type double patenting rejection still applies.

**Rejection of Claims 29, 36 and 70-71 under 35 USC §112**

As discussed above, the original claims have been canceled and replaced with new claims. As a result, Applicants believe the section 112 rejections have been rendered moot.

**Rejection of Claims 1-7, 10, 11, 14-18, 36, 39, 40 and 70 under 35 USC §102(e)**

Claims 1-7, 10, 11, 14-18, 36, 39, 40 and 70 were rejected under 35 U.S.C. §102(e) as being anticipated by Schreck, U.S. Patent No. 6,454,799. Applicants believe that the new claims are patentable over Schreck.

New claim 72 provides an annular support stent having a substantially circular profile in an expanded configuration and a plurality of longitudinally rigid support beams of fixed length. Although Applicants acknowledge the presence of the longitudinally rigid commissure posts 42 in Schreck, these are not part of a support stent having a substantially circular profile. Indeed, a preferred construction of the support stent 24 of Schreck is using a single piece of flat material which is first rolled into a tubular shape after which the commissure posts 42 are bent outward to project in the opposite direction from their original direction (see column 7, lines 18-32). As a result, a narrow space 62 exists between the commissure posts 42 and the exterior of the tubular support stent 24. See Fig. 3 where a lower portion of a flexible tubular member 20 extends into these spaces. Moreover, there is no disclosure of alternative stents or suggestions to modify the stent of Schreck so that it describes a substantially circular profile in which are provided the commissure posts 42. Accordingly, Applicants assert that claims 72 and its dependents are allowable over Schreck.

Claim 83 provides a support stent that is substantially tubular in its deployed state and having a plurality of longitudinally rigid support beams of fixed length distributed around a circumference thereof and extending substantially co-extensively with the support stent. The commissure posts 42 of Schreck, on the other hand, project substantially farther on an outflow end of a tubular base 40 of the support stent. Individual leaflets are formed by attaching commissures of the flexible tubular member 20 to the commissure posts 42 above the outflow

end of the tubular base 40. There is no discussion of altering the commissure posts 42 so they stand substantially co-extensively with the tubular base, and therefore Applicants assert that claim 83 and its dependents are allowable over Schreck.

Claim 96 provides a valve prosthesis device that has an outer support stent, an inner valve assembly, and a fabric layer positioned between the valve assembly and support stent and to which both are stitched. This is not disclosed or suggested in Schreck, and therefore Applicants assert that claim 96 and its dependents are allowable over Schreck.

**Rejection of Claims 8 and 33 under 35 USC §103(a)**

Claims 8 and 33 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Schreck in view of Boretos, et al. or Wheatley, et al. Applicants note that none of the new claims provide that the leaflets are made out of polyurethane.

**Rejection of Claims 9, 25 and 26 under 35 USC §103(a)**

Claims 9, 25, and 26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Schreck in view of Bessler, et al., USPN 5,855,601. It is believed that new claims 77, 89, and 101, which specify the material of the support stent, are allowable because they depend from allowable base claims.

**Rejection of Claims 21 and 22 under 35 USC §103(a)**

Claims 21 and 22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Schreck in view of Rosen, USPN 4,345,340. It is believed that new claims 78-79, 91-92, and 103-104, which recite radiopaque markers on the support stent, are allowable because they depend from allowable base claims.

**FEE DUE TO FILE THIS AMENDMENT**

Prior to the pending Office Action, a fee was paid for a maximum of 71 claims, with 4 of them being independent claims. The aforementioned claim additions and cancellations have not resulted in more than the original number of claims, and thus no claim fees are believed to be due to file this amendment.

Application Serial No. 10/051,002

Amdt. dated April 17, 2006

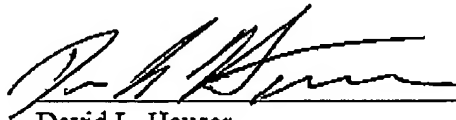
Reply to Office Action of February 8, 2006

**CONCLUSION**

In view of the above amendments and remarks, Applicants believe that new claims 72-107 are allowable in their present form. Should the Examiner have any remaining questions, the Examiner is encouraged to contact the attorney of record at the telephone number shown below.

Respectfully submitted,

Date: April 17, 2006



David L. Hauser  
Registration No. 42,643  
EDWARDS LIFESCIENCES LLC  
One Edwards Way  
Legal Department  
Irvine, California 92614  
Telephone: (949) 250-6878  
Facsimile: (949) 250-6850  
Customer No.: 30452